SEP 15 2011

SPINAL USA

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Pearl, MS 39208

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510(k) Summary

Date Summary Prepared:	July 11, 2011
Submitter Information:	Spinal USA 2050 Executive Drive Pearl, MS 39208
Contact Name: Phone: Fax: E-mail:	Frankie Cummins 601-420-4244 601-420-5501 fc@spinalusa.com
Device Trade Name:	Sure Lok Mini Posterior Cervical/Upper Thoracic System
Common Name:	Spinal Interlaminal Fixation Orthosis
Regulatory Number:	888.3050
Classification:	Class II
Product Code:	KWP
Predicate Device:	Synthes - Cervifix System (K991089) Alphatec - Solanas System (K052201) Seaspine - Sierra System (K072729)

INTENDED USE:
When intended to promote fusion of the cervical spine (Cl-C7) in skeletally mature patients, the Sure Lok Mini Posterior Cervical/Upper Thoracic System is indicated for the following:

-DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiologic studies)
-Spondylolisthesis

-Spinal Stenosis
-Fracture/dislocation
-Revision of previous cervical spine surgery
-Tumors

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for the purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical (C1-C7) spine.

DEVICE DESCRIPTION:
The Sure Lok Mini Posterior Cervical/Upper Thoracic System consists of polyaxial screws, rods and hooks. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from titanium alloy. The components will be provided non-sterile.

EQUIVALENT DEVICE:
Documentation was provided which demonstrated the Sure Lok Mini Posterior Cervical/Upper Thoracic System is substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

Components of the Sure Lok Mini Posterior Cervical/Upper Thoracic System are similar to the predicate systems. The design concept of the polyaxial pedicle screw of the Solanas and Sierra systems are similar to the Sure Lok Mini Posterior Cervical/Upper Thoracic system. The screw thread type, size and length are similar as is the polyaxial ball joint locking mechanism and rod clamping cap screw. The same applies to the rescue screw design. The cap screw torque applied to seat the cap screw is similar to the predicates. Screw angulation is also similar. Rod design is similar to the predicate systems. Rod diameter is either the same or larger. Rod lengths are similar to the predicates. Hook type, shape, size are similar to the predicates. Cross links, domino, and offsets are similar to the predicates. Material is the same as the predicates. Sterilization is the same as the predicates.

The following mechanical testing was performed on the Sure Lok Mini Posterior Cervical/Upper Thoracic System. Testing was performed according to ASTM F1717: Static Axial Compression Bending test, Static Torsion test, Dynamic Axial Compression Bending test, and Dynamic Torsion test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spinal USA
% Mr. Frankie Cummins
2050 Executive Drive
Pearl, Mississippi 39208

SEP 15 2011

Re: K112025
Trade/Device Name: Sure Lok Mini Posterior Cervical/
Upper Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: July 13, 2011
Received: July 15, 2011

Dear Mr. Cummins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Sure Lok Mini Posterior Cervical/Upper Thoracic System

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-DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiologic studies)
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-Spinal Stenosis
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-Revision of previous cervical spine surgery
-Tumors

The use of polyaxial screws is limited to placement in the upper.thoracic spine (T1-T3) for the purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical (C1-C7) spine.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112025